

# ESCCA 2019

An incredibly amazing experience...

## Driving laboratories to higher productivity

Diagnostic laboratories can be difficult places. They face excessive workloads that keep staff busy, are confronted with increasing demands of reduced turnaround time (TAT) and the constant requirements of efficiency, accuracy and high quality. Debbie Bruno of Ampath Laboratories, Pretoria, South Africa, knows it all too well. A leading centre for HIV monitoring in a country with one of the highest per-capita incidences of AIDS in the world, Debbie's laboratory is the quintessential, high workload, efficiency and quality-demanding environment. The need was, therefore, for a solution that combined automation, simplicity and consistency, while ensuring standardisation and flexibility. All this led Debbie Bruno and Ampath to the BD FACSDuet™ Automated Sample Preparation System, physically integrated with the BD FACSLytic™ Flow Cytometer, a walk-away, sample to answer solution that had the well-earned reputation of driving laboratories to higher productivity.

At ESCCA 2019, Debbie was our special guest at the BD Industrial Partner Presentation titled 'An incredibly amazing



experience'. In a frank and open interview moderated by Lori Apoll, BD clinical sales consultant, Debbie spoke about her lab, the challenges it faced and how the BD solution helped overcome them. The result was, in Debbie's own words, 'an incredibly amazing experience...'



## Ampath Laboratories, South Africa



Ampath Laboratories, South Africa

Ampath is the largest private pathology company in South Africa. Its headquarters are based in Pretoria, together with the national reference laboratories (NRL). Operating 24 hours a day, seven days a week, including holidays, the NRL performs a huge range of testing with the bulk of the work coming from smaller labs and more than 350 depots.

The CD4 lab, a part of the Immunology department, runs anywhere between 9000 and 14000 samples each month and encounters peak volumes in the months of January/February and July/August. As per South African Government guidelines, HIV monitoring (CD3, CD4, CD8 and HIV viral load) is done every six months with most tests scheduled for the beginning and middle of the year. The lab also establishes baseline values for new HIV patients. Many oncologists also use CD4 testing to monitor their patients. The CD4 tests are currently run on 6 BD FACS™ Sample Preparation Assistants and 3 BD FACSCanto™ Flow Cytometers.

### Heavy workload and other challenges

*'I need to eliminate any process inefficiency, reduce technicians' manual interventions to minimize mistakes and have the confidence that the lab produces the best quality results'*

– Debbie Bruno

In addition to the enormous sample volumes, Debbie's laboratory had problems with staff movement caused by manual operations. The technicians would collect their specimens in the pre-analytical section of the immunology lab, where the specimen lists are actioned, and the processed samples

stored. They would be moving back and forth around the central part of the CD4 lab between 6 sample preppers and the flow cytometers, due to all the manual steps involved. The bottleneck usually occurs prior to loading the samples on the flow cytometers, as the preparation is accomplished faster than the reading.

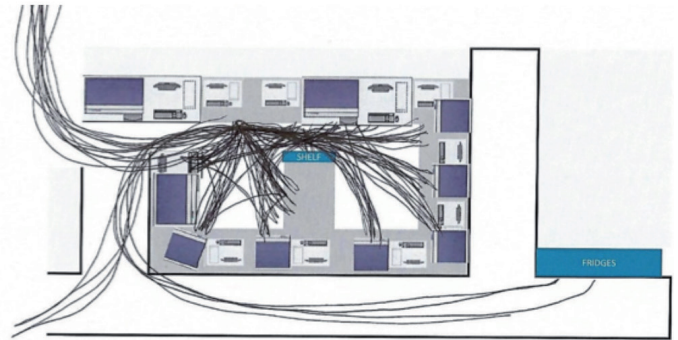


Diagram showing technician movements in the laboratory

The lab is already highly automated as turnaround time (TAT) is important, given the sample volumes, but there was a need for a standardised throughput to make it easier. Also, employing suitably qualified staff and managing down-sizing due to automation were important for managing TAT challenges.

An important consideration is to have a system with the ability to give clear CD4 results the first time. The lab's LIS or laboratory information system is set up to show historical CD4 and viral load results, and the staff review to determine if there are discrepancies. For example, if a drastic increase in CD4 count is seen compared to the previous test, the sample is re-run and a white cell count is performed. The lab runs two levels of internal quality control (CD4 normal and CD4 low) on all the instruments in use, processing six of each level every day. It was important, therefore, to streamline the instruments to reduce re-staining and manual gating. The result review process is also time-consuming and error-prone as it is done manually. While automation would not eliminate the manual error in the review, it would help by reducing the time to perform other tasks, allowing for more time to review the results.

Debbie's requirements, therefore, were to increase efficiency, minimise manual mistakes and produce quality results.

### Identifying the challenges – BD's Lean analysis

*'We even succeeded in modifying some of our current processes while the observation was on-going...it was a "quick-win", something I was not expecting!'*

– Debbie Bruno

The BD team that visited Ampath Laboratories analysed the entire workflow process and provided insights on where to focus and drive improvements. The Lean Six Sigma analysis identified five out of eight 'wastes', that could be improved upon. These were as follows

- Defects - caused by rework, scrap and incorrect information
- Motion - unnecessary movements by people
- Non-utilised talent - underutilising staff talents, skills and knowledge
- Extra processing - more work for higher quality than is required
- Waiting - waiting time for the next step in the process

Hands-on time was another parameter that the BD team included in its metrics. The BD lean assessment also showed that the error-prone steps fell into two categories:

- Related to the integrity of the specimen. For example: when re-barcoding a sample or when comparing with a previous result. This requires a solution that allows for sample traceability.
- Related to workflow-disrupting processing steps. For example, samples re-run due to insufficient reagent. Automation can remove manual errors and provide one single method for sample preparation.

The ultimate aim, according to Debbie Bruno, was to create a process that allowed only one way to do all the tasks. This would ensure consistency and avoid 'personal touches' or minor differences in results caused due to manual handling.

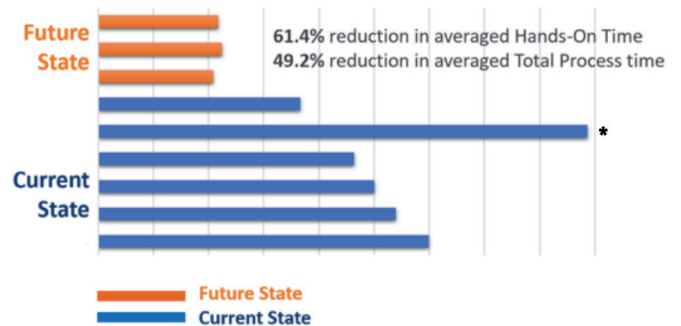
## The BD Solution and its impact



*'We want to make a process so that there is really ONLY ONE way to do them, no "personal touches", make them error-proof'* – Debbie Bruno

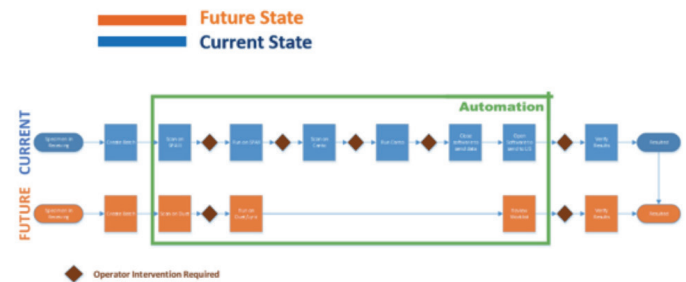
Debbie's laboratory tested the BD FACSDuet™ Automated Sample Preparation System physically integrated

with the BD FACSLyric™ Flow Cytometer. During the study, numerous scenarios were tested, keeping in mind the optimal performance needed for the laboratory. Actual patient batches were run on the current system and on the BD solution, and all the processes were timed from start to finish. The average amount of hands-on time with the new system was lower by 61.4%, with a 49.2% reduction in total process time. Even the removal of the outlier\* resulted in equally impressive metrics (56.2% and 42.5%)



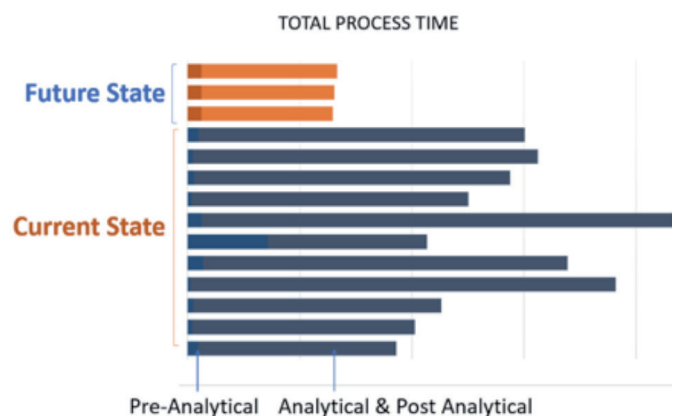
Reduction in hands on and total process times

Another great benefit of the BD solution is the reduction in the number of manual steps, mainly in the analytical part in which specimens are processed. Upon analysing the laboratory's current setup, it was found that despite the existing



Reduction in the number of manual steps

automation, operator intervention or manual handling was required in at least five steps. These are often delayed due to one staff member having to run multiple instruments. The



Reduction and consistency in processing time

existing software system requires the staggering of multiple runs, and the staff member must coordinate them. Any specimen problem needs to be dealt with before the run can start, resulting in delays to the next instrument in a cascading way. The BD FACSDuet™/BD FACSLytic™ system has only one manual step, which is loading the samples and pressing the 'on' button. The automation eliminates all the other problems. According to Debbie, Ampath has an impressive training program resulting in the staff getting hired by other laboratories. This is resulting in a quick turnover of the staff, and many 'personal touches' in the processes consequently. Increasing the level of automation with the introduction of the BD FACSDuet™/FACSLytic™ solution will provide more consistent results and its intuitive menu and functions would ensure minimised training time for new staff.

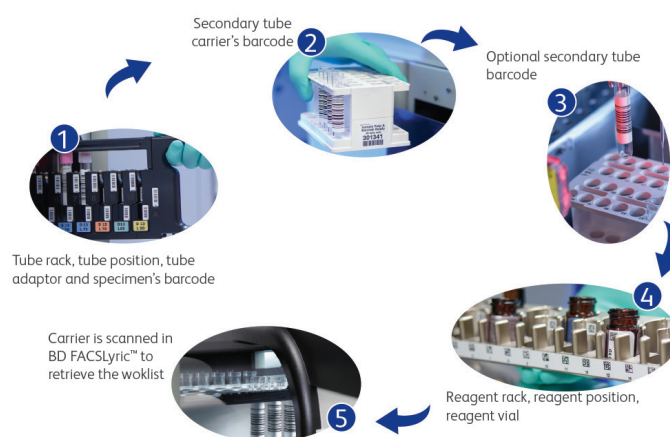


The BD FACSDuet/FACSLytic system has an integrated LIS.

For a lab dealing with a large number of samples, traceability is a key requirement. The BD FACSDuet™/FACSLytic™ system has an integrated LIS system which enhances the automation process. According to Debbie, this allows users to deal with any specimen issues right at the beginning of the process. In the existing system a defective barcode would involve stopping the process, relabelling the sample and rescanning, resulting in all the samples getting delayed. In the BD FACSDuet™, unreadable barcodes on the primary specimen can be easily managed without having to remove the specimen from the system for re-barcoding by either entering the ID manually (using two pass verification) or by skipping the specimen for that specific run. Either scenario ensures that a run is not disrupted by primary specimen ID label issues that have the potential to affect turnaround times.

Debbie is really impressed with the fact that the BD FACSDuet™/FACSLytic™ system delivers a complete sample and consumable traceability for each patient. Being a lab running HIV testing, traceability is crucial also in clinical trials and in

case of legal disputes. All the information related to each specimen and sample are saved in the software and easily retrievable to be made available in an audit process that Debbie's lab goes through three times a year. The barcoding on the BD FACSDuet™/FACSLytic™ system automatically tracks reagent expiry date and lot number across the entire sample process with reports that can be retrieved from the system. This eliminates all the manual steps in the reagent inventory tracking process.



Sample and consumable traceability

In addition to all the advantages stated, the integrated BD FACSDuet™/FACSLytic™ system proved to be very robust, running continuously for 16 hours. The high performance also allowed Debbie's team to evaluate the number of instruments they needed. This helped them save space and costs by choosing fewer instruments.

## Conclusion

In the end, Debbie and her team are really pleased with all the advantages the integrated BD FACSDuet™/FACSLytic™ system brings with it. The key requirements of increasing efficiency, reducing manual errors and improving quality, are all being met. This is extremely important as the ultimate beneficiaries are the patients. For Debbie and her team, working with the integrated BD FACSDuet™/FACSLytic™ system was, in her own words, 'An incredibly amazing experience'.

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